UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/804,626	03/09/2001	Leslie Lobel	62259/JPW/SHS	5559

7590 12/05/2003

John P. White
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, NY 10036

EXAMINER	
JIANG, DONG	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 12/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/804,626	LOBEL ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,7,16,18,24-26,32-42 and 44-47* is/are pending in the application.

4a) Of the above claim(s) *32-42 and 44-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 4, 7, 16, 18, and 24-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,2,4,7,16,18,24-26,32-42 and 44-47* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED OFFICE ACTION

Applicant's election with traverse of Group I invention, claims 1, 2, 4, 7, 16, 18 and 24-26, filed on 11 September 2003 is acknowledged. The traversal is on the ground(s) that Group I invention is directed to nucleic acids, cells, recombinant methods, and polypeptides produced thereby, and the rest of groups are directed to antibodies for the polypeptides and methods of using the antibodies and the polypeptides, therefore, groups I-IX are not independent, and that search and examination of Groups II-IX would not pose an undue burden one Group I has been searched. This is not found persuasive because, although the protein and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used in another and materially different process. As such, non-coextensive searches are required. Further, even though it is possible that a search of the prior art in regard to group I may reveal whether any prior art exists as to the other Groups, a search is aimed to find references that would render the invention obvious, as well as references directed to anticipation of the invention. Therefore, a search for one group is not adequate as to revealing references anticipating the other groups. Thus, independent searches of relevant literature in different areas of subject matter are required for different groups. Additionally, with current patent practice, a serious burden may be established by (A) separate classification thereof; (B) a separate status in the art when they are classifiable together; or (C) a different field of search. In the instant case, Group I is patentably distinct form Groups II-IX as shown by their separate classification, indicating each distinct subject has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. As stated in the MPEP 803, "a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP 802.02". Thus, search all groups would constitute an undue burden for the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

With respect to Inventions IV and V, directed to a method of using the polypeptide, they will be rejoined at such time as allowable subject matter is identified.

Currently, claims 1, 2, 4, 7, 16, 18, 24-26, 32-42 and 44-47 are pending. Claims 1, 2, 4, 7, 16, 18, and 24-26 are under consideration. Claims 32-42 and 44-47 are withdrawn from further consideration as being drawn to a non-elected invention.

Objections and Rejections under 35 U.S.C. 112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 is indefinite for failing to adequately point out what applicants see as the invention, as the host cell may produce a soluble polypeptides other than the soluble polypeptide encoded by the transformed or transfected vector. The claim should be amended to indicate the identity of the soluble polypeptide being produced.

Rejections Over Prior Art:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4, 7, 16, 18, and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hsueh et al., US5,925,549, and McCoy et al., US5,270,181.

Hsueh discloses a nucleic acid molecule encoding a chimeric protein comprising an extracellular ligand binding region (ELBR) of a human LH/CG receptor or a human FSH receptor, a protease recognition site, and a membrane anchor polypeptide, wherein ELBR contains all or a part of the extracellular portion of the receptor, and the chimeric polypeptide has ligand binding properties (column 4, lines 25-32, column 6, lines 53-64, and Figure 1B and 1C). Further, Hsueh teaches a method of recombinantly producing the fusion polypeptide, which further includes incubating the host cells in the presence of a protease recognizing the protease recognition site, to release the first segment of the chimeric polypeptide (column 5, lines 10-20). Hsueh does not teach a fusion protein comprising an extracellular domain of a human LH/CG receptor or a human FSH receptor, and thioredoxin.

McCoy teaches a fusion molecule comprising a DNA sequence encoding a thioredoxin protein fused to the DNA sequence encoding a selected heterologous peptide or protein (the abstract), an expression vector containing said fusion molecule, a host cell thereof, and a method for producing the fusion protein (column 2, line 56 to column 3, line 5). Further, McCoy teaches that the method permits the production of large amounts of heterologous peptides or proteins in a stable, soluble form, and that the heterologous peptide or protein retains the bioactivity (column 3, lines 64-66, and column 11, lines 8-10). Additionally, McCoy teaches that the fusion protein may itself be useful as a therapeutic without cleavage of the selected protein or peptide sequence therefrom when a human thioredoxin sequence is used (column 7, lines 57-60).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to make a fusion molecule comprising a DNA sequence encoding a thioredoxin protein as taught by McCoy, fused to the DNA sequence encoding an extracellular domain of a human LH/CG receptor or a human FSH receptor as taught by Hsueh using the method taught by McCoy as the method is generally useful for producing a selected

heterologous peptide or protein. The person of ordinary skill in the art would have been motivated to make such a fusion protein because of the advantages taught by McCoy that such fusion protein is stable, soluble and expressed at high level, and that the resulted fusion protein is useful as a therapeutic without cleavage. The person of ordinary skill in the art reasonably would have expected success because McCoy has demonstrated the successful expression of such fusion proteins (Examples 1-7).

Conclusion:

No claim is allowed.

Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

LORRAINE SPECTOR
PRIMARY EXAMINER

Dong Jiang, Ph.D.
Patent Examiner
AU1646
11/18/03